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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,128

10/21/2005

Yen Choo

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EXAMINER

TONGUE, LAKIA J

ART UNIT

PAPER NUMBER

1645

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/530,128	<b>Applicant(s)</b> CHOO, YEN	
	<b>Examiner</b> LAKIA J. TONGUE	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/7/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's response filed on February 2, 2009 is acknowledged. Claims 1, 2, 5-8, 13, 15 and 16 have been amended. Claims 3, 4 and 17-45 have been canceled. Claims 1, 2 and 5-16 are pending and under examination.

#### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on January 7, 2009 is in compliance with the provisions of 37 CFR 1.97 and has been considered. An initialed copy is attached hereto.

#### ***Objections Withdrawn***

2. In view of Applicant's amendment, the objection to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code (see for example pages 1 and 19) is withdrawn.

3. In view of Applicant's amendment, the objection of claim 4 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn. Applicant's cancellation of claim 4 renders the rejection of said claim moot.

***Rejections Maintained***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. The rejection of claims 1, 2, 4-8, 10 and 12-16 under 35 U.S.C. 102(b) as being anticipated by Nishikawa et al. (Development, 1998; 125: 1747-1757) is maintained for the reasons set forth in the previous Office action.

Applicant argues that:

1) Nishikawa does not describe a method for determining the effect of a plurality of culture conditions on a cell that includes the steps of a) providing a first set of groups of cell units each comprising one or more cells, and exposing said groups to desired culture conditions; b) subdividing one or more of said groups to create a further set of groups of cell units; c) exposing said further groups to further desired culture conditions; d) repeating steps (b)-(c) iteratively as required; and e) assessing the effect on a given cell unit of the culture conditions to which is has been exposed.

2) Since Nishikawa does not describe that the split-split or pool-split steps are repeated as described in claims 1 and 2, dependent claim 10 and 12-16 should be patentable over Nishikawa for at least the same reasons described above.

Applicant's arguments have been considered and are deemed non-persuasive.

The rejected claims are drawn to a method for determining the effect of a plurality of culture conditions on a cell comprising the steps of: a) providing a first set of groups of cell units each comprising one or more cells, and exposing said groups to desired culture conditions; b) subdividing one or more of said groups to create a further set of groups of cell units; c) exposing said further groups to further desired culture conditions; d) repeating steps (b)-(c) iteratively as required; and e) assessing the effect on a given cell unit of the culture conditions to which is has been exposed.

With regard to Points 1 and 2, the claims recite "repeating steps (b)-(c) iteratively as required". The Examiner is of the position that 'as required' implies that it may or may not be required, as 'as required' is defined as according to need or as needed.

As previously presented, Nishikawa et al. disclose a method of analyzing cell cultures. The method involves ES cells which were initially maintained on Mitomycin C treated layers in DMEM. The cells were then transferred to gelatin coated culture dishes to remove fibroblasts. Cells were then transferred (subdivided) to each well of IV collagen-coated 6-well cluster dishes and incubated in alpha MEM supplemented with FCS and 2ME. Moreover, Nishikawa et al. disclose that the cultured cells were harvested with a cell dissociation buffer and analyzed for expression of surface markers. The dishes were coated with gelatin, type I collagen or fibronectin and

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compared for the ability to support the differentiation of ES cells. Nishikawa et al. disclose that the atmosphere in the chamber holding the cells was 37°C (see page 1748; Cell Culture). Lastly, Nishikawa et al. disclose that cell layers were prepared in 96-well cluster dishes.

The method steps of the Nishikawa et al. are the same as the instantly claimed invention, the method of Nishikawa et al. necessarily determines the effect of a plurality of culture conditions on a cell.

5. The rejection of claims 1, 2 and 4-16 under 35 U.S.C. 102(e) as being anticipated by Scholl et al. (U.S.2004/0170965 A1) is maintained for the reasons set forth in the previous office action.

1) Scholl et al. do not describe a method for determining the effect of a plurality of culture conditions on a cell that includes the steps of a) providing a first set of groups of cell units each comprising one or more cells, and exposing said groups to desired culture conditions; b) subdividing one or more of said groups to create a further set of groups of cell units; c) exposing said further groups to further desired culture conditions; d) repeating steps (b)-(c) iteratively as required; and e) assessing the effect on a given cell unit of the culture conditions to which is has been exposed.

2) Since Scholl et al. do not describe that the split-split or pool-split steps are repeated as described in claims 1 and 2, dependent claim 10 and 12-16 should be patentable over Nishikawa for at least the same reasons described above.

Applicant's arguments have been considered and are deemed non-persuasive.

The rejected claims are drawn to a method for determining the effect of a plurality of culture conditions on a cell comprising the steps of: a) providing a first set of groups of cell units each comprising one or more cells, and exposing said groups to desired culture conditions; b) subdividing one or more of said groups to create a further set of groups of cell units; c) exposing said further groups to further desired culture conditions; d) optionally, repeating steps (b)-(c) iteratively as required; and e) assessing the effect on a given cell unit of the culture conditions to which is has been exposed.

With regard to Points 1 and 2, the claims recite "repeating steps (b)-(c) iteratively as required". The Examiner is of the position that 'as required' implies that it may or may not be required, as 'as required' is defined as according to need or as needed.

As previous presented, Scholl et al. disclose a method of cultivating cells. The cell lines were cultured to confluency in sterile polystyrene flasks in EMEM with HEPES, FBS, L-glutamine, and penicillin/streptomycin (see paragraph 0148). Scholl et al. disclose that the cells to be cultured were harvested by first rinsing source cell monolayers with Hank's Balanced Salt Solution (HBSS) without magnesium or calcium. Ten volumes of cell culture medium was added to each trypsinized cell suspension and the cells were repeatedly pipetted in order to produce near-single cell suspensions (see paragraph 0149).

Scholl et al. disclose that the cell mixture monolayers were produced by co-planting two distinct cell types at an equal volume of each diluted cell suspension. The cells were allowed to attach to the well surface by gravity for 30-60 minutes, and the inoculated microtiter plates were incubated for up to three days at 36°C in 5% CO<sub>2</sub> with

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95% relative humidity (see paragraph 0150). Moreover, Scholl et al. disclose that periodically during incubation, single and mixed monolayers were checked for overall viability. The mixed cell culture monolayers were also checked for the ability of the cell lines to co-exist and develop as a single cell sheet, with two distinct cell morphologies, at an approximately equal density of each cell type. At confluency, the cells were treated with a methylene blue staining solution to fix the cells and stain them a light blue in order to provide contrast for visualization using light microscopy (see paragraph 0151). Scholl et al. disclose that some of the mixed monolayers successfully grew as a mixed cell monolayer adhered to the well surfaces, exhibiting a smooth, evenly distributed monolayer (see paragraph 0152). Scholl et al. disclose that the cell lines are often supplied either in tubes, shell vials, or multi-well plates (e.g., microtiter plates). Lastly, Scholl et al. disclose that after inoculation of the cell line and an appropriate incubation time, confirmation of the presence of HSV in the sample can be accomplished using one or more of the many analytical methods (e.g., immunofluorescence, immunoperoxidase, nucleic acid probes, or substrates for virus-induced reporter genes) (see paragraph 0013).

The method steps of the Scholl et al. are the same as the instantly claimed invention, the method of Scholl et al. necessarily determines the effect of a plurality of culture conditions on a cell.



***Conclusion***

6. No claims are allowed.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/  
Supervisory Patent Examiner,  
Art Unit 1645

LJT  
5/11/09